



Food and Drug Administration
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December 5, 2014

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
FATIMA PACHECO
REGULATORY CLINICAL AFFAIRS SPECIALIST
511 BENEDICT AVENUE
TARRYTOWN NY 10591

Re: K143194

Trade/Device Name: ADVIA Centaur® Prolactin Master Curve Material (MCM),
ADVIA Centaur® Cortisol Master Curve Material (MCM)

Regulation Number: 21 CFR 862.1660

Regulation Name: Quality control material (assayed and unassayed)

Regulatory Class: I, Reserved

Product Code: JJX

Dated: October 31, 2014

Received: November 6, 2014

Dear Ms. Fatima Pacheco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k143194

Device Name
ADVIA Centaur® Prolactin Master Curve Material (MCM)

Indications for Use (Describe)

The ADVIA Centaur® Prolactin (PRL) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Prolactin assay.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

510(k) Number (if known)

k143194

Device Name

ADVIA Centaur® Cortisol Master Curve Material (MCM)

Indications for Use (Describe)

The ADVIA Centaur® Cortisol (COR) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Cortisol assay.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 006: 510(k) Summary

510(k) Summary – ADVIA Centaur Prolactin Master Curve Material

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: K143194

- 1. Applicant Information**

Mailing Address: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA

Contact Person: Fatima Pacheco
Regulatory Clinical Affairs Specialist

Phone Number: (914) 524-2450

Fax Number: (914) 524-3579

E-mail Address: fatima.pacheco@siemens.com

Date Prepared: November 25, 2014
- 2. Device Name**

Proprietary Name: ADVIA Centaur® Prolactin (PRL) Master Curve Material

Measurand: Quality Control materials for ADVIA Centaur PRL assay

Type of Test: Master Curve Material (MCM) for ADVIA Centaur PRL assay
21 CFR 862.1660, Quality Control Material

Regulation Section: Class I Reserved

Classification: JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

Products Code:

Panel: Clinical Chemistry (75)
- 3. Predicate Device Name**

Predicate 510(k) No: Elecsys Prolactin II CalCheck 5
K110613
- 4. Device Description:**

ADVIA Centaur® Prolactin Master Curve Material is an *in vitro* diagnostic product containing various levels of prolactin spiked in lyophilized equine serum with sodium azide (0.1%) and preservatives including amphotericin B. Each set contains ten levels (MCM1–10); with a reconstituted volume of 1.0 mL per level. MCM1 contains no analyte. The MCMs assigned values are lot-specific of target values: 0.00, 2.11, 4.61, 9.21, 26.0, 51.1, 82.9, 113, 161, and 218 ng/mL.

- | | |
|---|--|
| 5. <u>Intended Use:</u>
Indication for Use: | See Indications for Use Statement below:
The ADVIA Centaur® Prolactin (PRL) Master Curve Material is for <i>in vitro</i> diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Prolactin assay. |
| Special Conditions for Use Statement(s): | For prescription use only |
| Special Instrument Requirements: | ADVIA Centaur® Systems
A description of the ADVIA Centaur system is documented in K971418. Subsequent modifications to the instrument have been reviewed and cleared in K032525 and K041133. |
| 6. <u>Technological Characteristics and Substantial Equivalence Comparison with Predicate:</u> | A comparison of the device features, intended use, and other information demonstrates that the ADVIA Centaur PRL MCM is substantially equivalent to the predicate device as summarized in Table 1 . |

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device	Predicate Device
Item	ADVIA Centaur PRL MCM	Elecsys Prolactin II CalCheck 5
Intended Use	The ADVIA Centaur Prolactin (PRL) Master Curve Material is for <i>in vitro</i> diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Prolactin assay.	The Elecsys Prolactin II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Prolactin II reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Prolactin	Same
Use	Multiple Use	Same
Storage	2–8°C	Same
Form	Lyophilized	Same
Matrix	Equine serum	Same
DIFFERENCES		
Levels	10	5
Stability	Unopened – Stable when stored unopened at 2–8°C for 29 months. Opened (Reconstituted) – Stable when stored at 2–8°C for 28 days; or on-board for 4 hours.	Unopened – Stable at 2–8°C up to the expiration date printed on the bottle labels. Reconstituted – Stable for 4 hours at 20–25°C.

7. Standard/Guidance Document References

The following recognized standard and guidance documents were used:

- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

8. Test Principle

The MCMs are specifically intended for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur assays for use on the ADVIA Centaur systems. Customers may use MCMs for bi-annual calibration verification checks of the assay range and linearity in order to meet the requirements of hospital accreditation bodies.

9. Performance Characteristics

9.1 Analytical performance:

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Analytical Specificity*
- *Assay cut-off*
- *Method Comparison Studies*
- *Clinical Studies (Sensitivity, Specificity, and cut-off)*

9.2 Non-Clinical Performance Testing

The following studies were conducted on the ADVIA Centaur XP system.

9.2.1 *Stability Studies*

Stability studies were conducted to support the shelf life (unopened) and reconstituted material for the ADVIA Centaur PRL MCMs to ensure that it maintains optimal product performance throughout the established shelf-life. The data supports the stability claims detailed in the ADVIA Centaur PRL MCM Instructions for Use.

The following stability studies were performed for ADVIA Centaur PRL MCM:

- Real Time/Shelf Life (unopened) Stability
- In Use Open Vial (reconstituted) stored at 2–8°C Stability
- On-Board Stability

Real time shelf-life studies (unopened): Test PRL MCMs were stored unopened at 2–8°C and tested at T=0 and at the following time points: 12 months, 18 months, and 30 months. Shelf life claims are based upon real time stability carried out one month after the duration claimed. Real time shelf-life stability studies of MCMs were determined by comparison of dose recoveries to the T=0 dose recovery results. Acceptance criteria for the real-time stability study were met up to the 30 months' time point, which supports a shelf-life claim of 29 months. Storage shelf-life (unopened) at 2–8°C is indicated by the expiration date on the vial label.

In-Use Open Vial (Reconstituted): Test PRL MCMs were reconstituted, each level pooled, aliquotted and stored at 2–8°C, tested in 5 replicates per level at T=0, 7, 14, 21, 28, and 29 days. Acceptance criteria for the open vial (reconstituted) stability study were met to the 29 days' time point, which supports the open vial claim of 28 days when properly stored at 2–8°C.

On-board Stability: Pooled aliquots of test PRL MCMs in sample cups were stored on the ADVIA Centaur system and measured at time point T=0, 2, 4 and 5 hours. On-board stability studies of MCMs were determined by comparison of dose recoveries to the T=0 dose recovery results. Acceptance criteria for the on-board stability study were met up to 5 hours, which supports the on-board stability claim for 4 hours.

Stability Acceptance Criteria

The stability specifications acceptance criteria for the ADVIA Centaur PRL MCM are as follows:

- Real Time/Shelf life (Unopened): The dose recovery for MCM1 and % dose recovery for MCM2–10 met the requirements of the acceptance criteria and no adverse trends.
- In-Use Open Vial (Reconstituted): The dose recovery for MCM1 and the % dose recovery MCM2–10 met the requirements of the acceptance criteria.
- On-Board: The dose recovery for MCM1 and the % dose recovery for MCM2–10 met the requirements of the acceptance criteria.

9.2.2 Value Assignment

The ADVIA Centaur PRL MCMs are value assigned using assigned reference calibrators and MCMs. The assigned reference calibrators are prepared using Prolactin stock and are traceable to internal material which is standardized against World Health Organization (WHO) 3rd IRP for human Prolactin 84/500 reference material. The MCMs are manufactured using qualified materials and measurement procedures.

For each new PRL MCM lot manufactured, MCM1 is run in 5 replicates on two separate runs using one reagent kit lot. A nested testing run protocol is used for MCM2–MCM10 value assignment. This consists of running alternating samples of the reference and new MCM level in the same run. MCM2–MCM10 were tested on 20 replicates in total, comprised of one run and four sample cups run in 5 replicates on one system and one reagent kit lot. This protocol is designed to remove system and run variation. The new MCM doses must fall within the final value assignment specification for PRL MCMs. The MCMs dose values are generated using the two-point calibration. The new MCM dose is calculated based on the relationship between the observed reference MCM dose and its assigned value. A performance verification run consisting of 6 replicates of each MCM level is run using one instrument, one reagent kit lot and Bio-Rad controls. The mean MCM doses of the new MCM lot manufactured must fall within the customer range specifications.

The target for MCM1 is assigned a 0.0 dose. MCM1 is analyte-free basepool comprising of only the matrix and preservatives. The quality control specifications and final value assignment limits for PRL MCM ensure that MCM1 measures at or below the PRL assay sensitivity limit. MCM10 targeted greater

than the assay range is diluted with the MCM1 to meet the reportable range of the assay.

9.2.3 Expected Values

The expected values are the lot-specific assigned values obtained at value assignment and the lot-specific assigned ranges are the lot-specific customer ranges are established per % interval as below.

MCM Level	% Interval
MCM1	N/A
MCM2	40%
MCM3	25%
MCM4	25%
MCM5	25%
MCM6	25%
MCM7	25%
MCM8	25%
MCM9	25%
MCM10	20%

Example Lot-specific target and assigned values are provided in the ADVIA Centaur PRL MCM lot-specific value sheet in the example provided in **Table 2**.

Table 2: Example Lot-specific PRL MCM Target and Assigned Values

MCM level	Target Values (ng/mL)	Assigned Values (ng/mL)
MCM1	0.00	0.00
MCM2	2.11	2.02
MCM3	4.61	5.21
MCM4	9.21	9.09
MCM5	26.0	25.9
MCM6	51.1	52.0
MCM7	82.9	87.4
MCM8	113	124
MCM9	161	148
MCM10	218	243
Assay Range	0.3–200 ng/mL	

9.2.4 Traceability

The ADVIA Centaur Prolactin assay is traceable to World Health Organization (WHO) 3rd IRP for Prolactin (84/500). Assigned values for calibrators and MCMs are traceable to this standardization. The PRL MCMs are manufactured using qualified materials and measurement procedures.

10. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

11. Conclusion

The ADVIA Centaur PRL Master Curve Material (MCM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys Prolactin II CalCheck 5. Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur PRL Master Curve Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.



(Bundled) Abbreviated 510(k) Premarket Notification
ADVIA Centaur® Prolactin and Cortisol Master Curve Material (MCM)

510(k) Summary – ADVIA Centaur COR Master Curve Material

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: K143194

- 1. Applicant Information**
Mailing Address: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA

Contact Person: Fatima Pacheco
Regulatory Clinical Affairs Specialist

Phone Number: (914) 524-2450
Fax Number: (914) 524-3579
E-mail Address: fatima.pacheco@siemens.com
Date Prepared: November 25, 2014
- 2. Device Name**
Proprietary Name: **ADVIA Centaur® COR Master Curve Material**
Measurand: Quality Control materials for ADVIA Centaur COR assay
Master Curve Material (MCM) for ADVIA Centaur COR assay
Type of Test: 21 CFR 862.1660, Quality Control Material

Regulation Section: Class I Reserved
Classification: JJX – Single (Specified) Analyte Controls (Assayed and
Unassayed)
Products Code: Clinical Chemistry (75)
Panel:
- 3. Predicate Device Name**
Predicate 510(k) No: Elecsys Cortisol CalCheck
K000576
- 4. Device Description:** ADVIA Centaur® Cortisol Master Curve Materials is an *in vitro* diagnostic product containing various levels of cortisol in lyophilized human plasma with sodium azide. Each set contains seven lyophilized levels (MCM1–7); with a reconstituted volume of 1.0 mL each. MCM1 contains no analyte. The COR MCMs assigned values are lot-specific of target values: 0.00, 1.00, 2.00, 6.00, 12.0, 30.0, and 80.0 µg/dL.
- 5. Intended Use:** See Indications for Use Statement below:
Indication for Use: The ADVIA Centaur® Cortisol (COR) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Cortisol assay.

Special Conditions for Use Statement(s): For prescription use only

**Special Instrument
Requirements:**

ADVIA Centaur® Systems

A description of the ADVIA Centaur system is documented in K971418. Subsequent modifications to the instrument have been reviewed and cleared in K032525 and K041133.

**6. Technological Characteristics
and Substantial Equivalence
Comparison with Predicate:**

A comparison of the device features, intended use, and other information demonstrates that the ADVIA Centaur COR MCM is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device	Predicate Device
Item	ADVIA Centaur COR MCM	Elecsys Cortisol CalCheck
Intended Use	The ADVIA Centaur Cortisol (COR) MCM is for <i>in vitro</i> diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Cortisol assay.	For use in the verification of the calibration established by the Elecsys Cortisol reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Cortisol	Same
Use	Multiple Use	Same
Storage	2–8°C	Same
Form	Lyophilized	Same
DIFFERENCES		
Matrix	Human Plasma	Human Serum
Levels	7	3
Stability	Unopened – Stable when stored unopened at 2–8°C for 22 months. Opened (Reconstituted) – Stable when stored at 2–8°C for 14 days; or on-board for 4 hours.	Unopened – Stable at 2–8°C up to the expiration date printed on the bottle labels. Opened (Reconstituted) – Stable for 4 hours at 20–25°C.

7. Standard/Guidance Document References

The following recognized standard and guidance documents were used:

- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

8. Test Principle

The MCMs are specifically intended for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur assays for use on the ADVIA Centaur systems. Customers may use MCMs for bi-annual calibration verification checks of

the assay range and linearity in order to meet the requirements of hospital accreditation bodies.

9. Performance Characteristics

9.1 Analytical performance:

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Analytical Specificity*
- *Assay cut-off*
- *Method Comparison Studies*
- *Clinical Studies (Sensitivity, Specificity, and cut-off)*

9.2 Non-Clinical Performance Testing

The following studies were conducted on the ADVIA Centaur XP system.

9.2.1 *Stability Studies*

Stability studies were conducted to support the shelf life unopened and reconstituted material for the ADVIA Centaur COR MCMs to ensure that it maintains optimal product performance throughout the established shelf-life. The data supports the stability claims detailed in the ADVIA Centaur COR MCM Instructions for Use.

The following stability studies were performed for ADVIA Centaur COR MCM:

- Real Time/Shelf Life (Unopened) Stability
- In Use Open Vial (Reconstituted) stored at 2–8°C Stability
- On-Board Stability

Real time shelf-life studies (unopened): Test COR MCMs were stored unopened at 2–8°C and tested at T=0 and at the following time points: 12 months, 18 months, and 23 months. Shelf life claims are based upon real time stability carried out one month after the duration claimed. Real time shelf-life stability studies of MCMs were determined by comparison of dose recoveries to the T=0 dose recovery results. Acceptance criteria for the real-time stability study were met up to the 23 months' time point, which supports a shelf-life claim of 22 months. Unopened storage shelf-life is indicated by the expiration date on the vial label.

In-Use Open Vial (Reconstituted): Test COR MCMs were reconstituted, each level pooled, aliquotted and stored at 2–8°C, tested in 5 replicates per level at T=0, 2, 4, 7, 11, 14, and 15 days. Acceptance criteria for the open vial (reconstituted) stability study were met to the 15 days' time point, which supports the open vial claim of 14 days when properly stored at 2–8°C.

On-board Stability: Pooled aliquots of test COR MCMs in sample cups were stored on the ADVIA Centaur system and measured at time point T= 0, 2, 4 and 5

hours. Acceptance criteria for the on-board stability study were met up to 5 hours, which supports the on-board stability claim for 4 hours.

Stability Acceptance Criteria

The stability specifications acceptance criteria for the ADVIA Centaur COR MCM are as follows:

- Real Time/Shelf life (Unopened): The dose recovery for MCM1 and % dose recovery for MCM2–7 met the requirements of the acceptance criteria and no adverse trends.
- In-Use Open Vial (Reconstituted): The dose recovery for MCM1 and % dose recovery for MCM2–7 met the requirements of the acceptance criteria.
- On-Board: The dose recovery for MCM1 and % dose recovery for MCM2–7 met the requirements of the acceptance criteria.

9.2.2 *Value Assignment*

The ADVIA Centaur COR MCMs are value assigned using assigned reference calibrators and MCMs. The assigned reference calibrators are prepared using cortisol stock traceable analytically prepared internal material which is traceable to gas-chromatography-mass spectroscopy (GCMS). The MCMs are manufactured using qualified materials and measurement procedures.

For each new COR MCM lot manufactured, MCM1 is run in 5 replicates on two separate runs using one reagent kit lot. A nested testing run protocol is used for MCM2–MCM7 value assignment. This consists of running alternating samples of the reference and new MCM level in the same run. MCM2–MCM7 were tested on 20 replicates in total, comprised of one run and four sample cups run in 5 replicates on one system and one reagent kit lot. This protocol is designed to remove system and run variation. The new MCM doses must fall within the final value assignment specification for COR MCMs. The MCMs dose values are generated using the two-point calibration. The new MCM dose is calculated based on the relationship between the observed reference MCM dose and its assigned value. A performance verification run consisting of 6 replicates of each MCM level is run using one instrument, one reagent kit lot and Bio-Rad controls. The mean MCM doses of the new MCM lot manufactured must fall within the customer range specifications.

The target for MCM1 is assigned a 0.0 dose. MCM1 is analyte-free basepool comprising of only the matrix and preservatives. The quality control specifications and final value assignment limits for COR MCM ensure that MCM1 measures at or below the Cortisol assay sensitivity limit. MCM7 targeted greater than the assay range is diluted with the MCM1 to meet the reportable range of the assay.

9.2.3 Expected Values

The expected values are the lot-specific assigned values obtained at value assignment and the lot-specific assigned ranges are the lot-specific customer ranges are established per % interval as below.

MCM Level	% Interval
MCM1	N/A
MCM2	35
MCM3	30
MCM4	30
MCM5	30
MCM6	30
MCM7	20

Example Lot-specific target and assigned values are provided in the ADVIA Centaur COR MCM lot-specific value sheet in the example provided in **Table 2**.

Table 2: Example Lot-specific COR MCM Target and Assigned Values

MCM Level	Target Values (µg/dL)	Assigned Values (µg/dL)
MCM1	0.00	0.0
MCM2	1.00	1.17
MCM3	2.00	1.96
MCM4	6.00	6.99
MCM5	12.0	12.5
MCM6	30.0	27.1
MCM7	80.0	80.3
Assay Range	0.20–75 µg/dL	

9.2.4 Traceability

The ADVIA Centaur Cortisol assay is standardized using internal standards manufactured analytically which are traceable to gas chromatography-mass spectroscopy (GCMS). Assigned values for calibrators and MCMs are traceable to this standardization. The COR MCMs are manufactured using qualified materials and measurement procedures.

10. **Proposed Labeling**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

11. **Conclusion**

The ADVIA Centaur COR Master Curve Material (MCM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys Cortisol CalCheck. Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur COR Maser Curve Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.